1. IDENTIFICATION OF THE SUBSTANCE / MIXTURE AND OF THE COMPANY / UNDERTAKING

1.1 PRODUCT IDENTIFIER

Product name:	**Catalog number:**
Seraline® Zöliakie-3 IgG	LIA-001-3 G
Seraline® Zöliakie-3 IgA	LIA-001-3 A
Seraline® ANA IgG	
Seraline® ANA-5 IgG	LIA-002-5 G
Seraline® ANA-8D IgG	LIA-002-8D G
Seraline® ANA-8N IgG	LIA-002-8N G
Seraline® ANA-9D IgG	LIA-002-9D G
Seraline® ANA-9N IgG	LIA-002-9N G
Seraline® ANA-12 IgG	LIA-002-12 G
Seraline® ANA-13 IgG	LIA-002-13 G
Seraline® ANA-15 IgG	LIA-002-15 G
Seraline® ANA-17 IgG	LIA-002-17 G
Seraline® Vaskulitis IgG	
Seraline® Vaskulitis-2 IgG	LIA-003-2 G
Seraline® Vaskulitis-3 IgG	LIA-003-3 G
Seraline® HepAk IgG	
Seraline® HepAk-6 IgG	LIA-004-6 G
Seraline® HepAk-7 IgG	LIA-004-7 G
Seraline® HepAk-8 IgG	LIA-004-8 G
Seraline® Anti-Yersinia-6 IgG	LIA-005-6 G
Seraline® Anti-Yersinia-6 IgG	LIA-005-6 G-12
Seraline® Anti-Yersinia-6 IgA	LIA-005-6 A
Seraline® Anti-Yersinia-6 IgA	LIA-005-6 A-12
Seraline® Anti-Borrelia-8 IgG	LIA-006-8 G
Seraline® Anti-Borrelia-8 IgG	LIA-006-8 G-12
Seraline® Anti-Borrelia-8 IgM	LIA-006-8 M
Seraline® Anti-Borrelia-8 IgM	LIA-006-8 M-12
Seraline® Anti-Helicobacter-6 IgG	LIA-007-6 G
Seraline® Anti-Helicobacter-6 IgA	LIA-007-6 A
Seraline® Anti-Treponema-4 IgG	LIA-010-4 G
Seraline® Anti-Treponema-4 IgM	LIA-010-4 M
Serablot® Anti-Francisella tularensis IgG	WB-003 G

1.2 RELEVANT IDENTIFIED USES OF THE SUBSTANCE OR MIXTURE AND USES ADVISED AGAINST

Membrane based screening tests for antibodies in human medicine.
Relevant identified use PROC15: Laboratory chemical
Reserved for industrial and professional use.

1.3 DETAILS OF THE SUPPLIER OF THE SAFETY DATA SHEET

Seramun Diagnostica GmbH
Spreenhagener Straße 1
15754 Heidesee
GERMANY
Phone: +49 33767-791-10
Fax: +49 33767-791 99
E-mail: info@seramun.com

1.4 EMERGENCY TELEPHONE NUMBER

Phone: +49 33767-791-10 available only during office hours.

2. HAZARDS IDENTIFICATION

2.1 CLASSIFICATION OF THE SUBSTANCE OR MIXTURE

According the EU-edict (EC) 1272/2008 modified by (EC) 2016/1179 the conjugate solutions are classified as reproductive toxic (Repr. 1B, H360D).

Because of the preservative it may be dangerous for water organisms.

2.2 LABEL ELEMENTS

Applicable for the conjugate solutions:

Pictogram	
Signal word	Danger!
Hazard class	reproductive toxity Repr. 1B
Hazard Statement(s)	H360D: May damage the unborn child.
Precautionary Statement(s)	P280: Wear protective gloves/protective clothing/eye protection/face protection

Note: According the EU-edict (EC) 1272/2008, article 1, 5 (d) the labelling shall not apply to IVD as defined in the Directive 98/79/EC.

2.3 OTHER HAZARDS

Chemicals bear specific risks. That's why these are only handled by qualified staff in compliance with health and safety regulations.
None of the components is listed as PBT or vPvB relevant.

3. COMPOSITION / INFORMATION ON INGREDIENTS

3.1 SUBSTANCES

All products are mixtures.

3.2 MIXTURES

Wash- and Incubation Buffer:	casein containing buffer with inorganic salts and preservative Concentrations of dangerous components according to (EC) 1272/2008 are below the limits of concentration mentioned in the law.
Conjugate solution:	Tris-buffer, bovine serum albumin, inorganic salts, supplements and preservatives, as active substances IgG (goat or sheep) and horseradish peroxidase (EC1.11.1.7). The bovine serum albumin was derived from bovine blood collected at USDA licensed establishment

Dangerous components according to (EC) 1272/2008:

REACH Register-number	EINECS	CAS-No.	name	percent-tage	symbol	H-statements
01-2119472430-46-XXXX	212-828-1	872-50-4	N-Methyl-2-pyrrolidone	< 2.0	 Danger!	H315, H319, H360D, H335

The full text of H-statements is in article 16

Test strips nitrocellulose membrane backed on plastic material

Dangerous components according to (EC) 1272/2008:

REACH Register-number	EINECS	CAS-No.	name	percent-tage	symbol	H-statements
not available	none	9004-70-0	nitrocellulose, backed	10	 Danger!	H228

The full text of H-statements is in article 16

substrate solution: aqueous solution of TMB, hydrogen peroxide, containing citrate and preservative
Concentrations of dangerous components according to (EC) 1272/2008 are below the limits of concentration mentioned in the law

4. FIRST AID MEASURES

4.1 DESCRIPTION OF FIRST AID MEASURES

General advice
Consult a physician. Show this safety data sheet to the doctor in attendance.

If inhaled
If breathed in, move the concerned person into fresh air. In case of apnoea, give artificial respiration. Consult a physician.

In case of skin contact
Wash off with plenty of water. Consult a physician.

In case of eye contact
Rinse the opened eye for several minutes with running water, if necessary remove contact lenses. Consult an ophthalmologist.

If swallowed
Never give anything by mouth to an unconscious person.
Rinse mouth with water, drink about 300 ml water, consult a physician.

4.2 MOST IMPORTANT SYMPTOMS AND EFFECTS, BOTH ACUTE AND DELAYED

No data available

4.3 INDICATION OF ANY IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT NEEDED

No data available

5. FIREFIGHTING MEASURES

5.1 EXTINGUISHING MEDIA

Suitable extinguishing media
For the test stripes water,
otherwise water spray, alcohol resistant foam, solid extinguishing agent or carbon dioxide.

5.2 SPECIAL HAZARDS ARISING FROM THE SUBSTANCE OR MIXTURE

The only flammable component is the test stripe. Because of the small amount (< 0.5 g per test kit) no danger is caused. The further components are inflammable; extinguishing measures should therefore be prepared for an environmental fire.
In case of fire toxic vapors, e.g. nitric oxide and carbon monoxide, can be released.

5.3 ADVICE FOR FIREFIGHTERS

Wear breath protective mask and protective clothes if necessary during fire fighting.

6. ACCIDENTAL RELEASE MEASURES

6.1 PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES

Use personal protective equipment. Avoid breathing vapor/mist/gas. Care for appropriate ventilation.

6.2 ENVIRONMENTAL PRECAUTIONS

Keep away from drains. Avoid contamination of water or soil.

6.3 METHODS AND MATERIAL FOR CONTAINMENT AND CLEANING UP

Suck up with inert absorbance material and dispose as hazardous waste. Keep in a suitable, closed container.

6.4 REFERENCE TO OTHER SECTIONS

For disposal considerations see chapter 13.

7. HANDLING AND STORAGE

7.1 PRECAUTIONS FOR SAFE HANDLING

No smoking, eating, drinking, chewing gum or storage of food or beverages in the working laboratories. Wash hands after work. Remove safety clothing before entering a refreshment room.

7.2 CONDITIONS FOR SAFE STORAGE, INCLUDING ANY INCOMPATIBILITIES

Store tightly closed on a cool dry place. Reseal opened bottles carefully and store in an upright position.

Recommended storage temperature: 2-8°C

Storage classification: 12 (non flammable liquids)
segregate from: class1 (explosives)
class 4.1A (flammable solids)
class 4.3 (dangerous when wet)
class 6.2 (infectious)
class 7 (radioactive)

Further information:
Store separated from foodstuffs.
Protect from unauthorized access.

7.3 SPECIFIC END USE(S)

Use only in accordance to the manual.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 CONTROL PARAMETERS

EINECS	name	limit value according to MAK (TRGS 900)	limit value according to BGW (TRGS 903)
212-828-1	N-Methyl-2-pyrrolidone	82 mg/m^3	150 mg/l urine at the end of a shift, parameter: 5-Hydroxy-N-Methyl-2-pyrrolidone

If the products are used according to the instructions, no air pollution is to be expected.

8.2 EXPOSURE CONTROLS

Consider the usual good hygiene and safety practice by handling chemicals.
Pregnant women should strictly avoid inhalation or skin contact.

Personal protective equipment

Eye/face protection: Safety glasses with side shields conforming to EN 166 (EU), NIOSH (US)

Skin protection: protective gloves of nitril rubber (thickness min. 0.28 mm, AQL1,5) or nature latex (thickness min. 0.22 mm, AQL 1,5), satisfying the norm EN 374.

Body protection: impermeable protective clothing, the kind of protective equipment hast o be selected depending from concentration and amount of dangerous substance at the specific workplace.

Respiratory protection: not required, if handled according to the intended use. In case of a divergent risk assessment use a full-face respirator with multi-purpose combination respirator cartridge Type ABEK (EN 14387).

Environmental exposure controls: Keep away from drains, water or soil.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 INFORMATION ON BASIC PHYSICAL AND CHEMICAL PROPERTIES

component	description	colour	odour
Wash- and Incubation Buffer	liquid product	yellowish-white opalescent	characteristic
Conjugate Solution	liquid product	IgG: red IgA: violet IgM: green	odourless
Test strip	solid product	white	odourless
Substrate Solution	liquid product	colourless to pale yellow	characteristic

component	pH-value	boiling point	Flash point	Explosive properties
Wash- and Incubation Buffer	6.2 – 6.4	101 °C	not applicable	non
Conjugate Solution	7.3 – 7.5	102 °C	not applicable	non
Test strip	not applicable	not applicable	not applicable	non
Substrate Solution	4.9 – 5.1	102 °C	not applicable	non

component	Oxidising properties	Vapour pressure	relative density
Wash- and Incubation Buffer	non	not measured	1.11 g/ml
Conjugate Solution	non	not measured	1.043 g/ml
Test strip	non	not applicable	not measured
Substrate Solution	non	not measured	1.013 g/ml

component	solubility	Water solubility	Viscosity
Wash- and Incubation Buffer	complete soluble/miscible in protic solvents	complete soluble/miscible	not measured
Conjugate Solution	complete soluble/miscible in protic solvents	complete soluble/miscible	not measured
Test strip	dissolved by aprotic solvents	insoluble	not applicable
Substrate Solution	complete soluble/miscible in protic solvents	complete soluble/miscible	not measured

9.2 OTHER INFORMATION

No further dangerous properties known.

10. STABILITY AND REACTIVITY

10.1 REACTIVITY

No data available.

10.2 CHEMICAL STABILITY

No data available.

10.3 POSSIBILITY OF HAZARDOUS REACTIONS

No data available.

10.4 CONDITIONS TO AVOID

Light, heat, moisture (will not cause a dangerous reaction, but destroys the quality of the products).
Sources of ignition (naked flame , sparks) (test strips are flammable).

10.5 INCOMPATIBLE MATERIALS

Oxidizing agents, metals (will not cause a dangerous reaction, but destroys the quality of the products).

10.6 HAZARDOUS DECOMPOSITION PRODUCTS

Dangerous decomposition products are not known.

11. TOXICOLOGICAL INFORMATION

11.1 INFORMATION ON TOXICOLOGICAL EFFECTS

(a) acute toxicity

Component	valuation	value	species
N-Methyl-2-pyrrolidone	LD_{50} (oral) LC_{50} (inhalativ)	3598 mg/kg >5.1 mg/l	rat rat

(b) skin corrosion/irritation

Component	valuation	value	species
N-Methyl-2-pyrrolidone	LD_{50} (dermal)	8000 mg/kg	rabbit

Risk of skin resorption (conjugate solution).
(c) serious eye damage/irritation
No information available
(d) respiratory or skin sensitization
No information available
(e) germ cell mutagenicity
No information available
(f) carcinogenicity
No information available
(g) reproductive toxicity
For conjugate solution: May damage the unborn child: N-Methyl-2-pyrrolidone (Repr. 1B)
(h) STOT-single exposure
May cause respiratory irritation.
(i) STOT-repeated exposure
No specific target organ toxicant, repeated exposure
(j) aspiration hazard
No information available

11.2 FURTHER TOXICOLOGICAL INFORMATION

Quantitative data on the toxicity of the mixtures are not available.
Calculation of ATE according to (EC) 1272/2008, Appendix I: see section 15.1.
Hazardous properties cannot be excluded but are unlikely when the products are handled appropriately.
Further data:
Handle in accordance with good industrial hygiene and safety practice.

12. ECOLOGICAL INFORMATION

12.1 TOXICITY

N-Methyl-2-pyrrolidone:

Spezies	Art	Wert
bluegill (Lepomis macrochirus)	LC_{50} (mg/l/96h)	832
gold orfe (Leuciscus idus)	LC_{50} (mg/l/96h)	> 500
green alga (Desmodesmus subspicatus)	IC_{50} (mg/l/72h)	> 500
invertebrates (Daphnia magna)	EC_{50} (mg/l/48h)	4897

12.2 PERSISTENCE AND DEGRADABILITY

Biological degradability:

substance	Value
N-Methyl-2-pyrrolidone easily biologically degradable	> 90%/20d

12.3 BIOACCUMULATIVE POTENTIAL

Distribution: log P(o/w): ≤ 4 (for N-Methyl-2-pyrrolidone)
There is no Bioaccumulation expected

12.4 MOBILITY IN SOIL

No data available.

12.5 RESULTS OF PBT AND VPVB ASSESSMENT

None of the components is listed as PBT or vPvB relevant.

12.6 OTHER ADVERSE EFFECTS

No further effects known.

If used appropriately, no ecological problems are to be expected

13. DISPOSAL CONSIDERATIONS

13.1 WASTE TREATMENT METHODS

Products:

Disposal should be made in accordance with national and local regulations and laws.

Packaging:
Emptied packaging can be given to local recycling or waste disposal.

14. TRANSPORT INFORMATION

14.1 UN NUMBER

ADR/RID: - IMDG: - IATA: -

14.2 UN PROPER SHIPPING NAME

ADR/RID: No dangerous goods IMDG: No dangerous goods IATA: No dangerous goods

14.3 TRANSPORT HAZARD CLASS(ES)

ADR/RID: - IMDG: - IATA: -

14.4 PACKING GROUP

ADR/RID: - IMDG: - IATA: -

14.5 ENVIRONMENTAL HAZARDS

ADR/RID: No IMDG: Marine pollutant no IATA: No

14.6 SPECIAL PRECAUTIONS FOR USER

According special regulation ADR 286 /IATA A122: Backed membranes of nitrocellulose with < 0.5 g, individually packed, are not restricted.

14.7 TRANSPORT IN BULK ACCORDING TO ANNEX II OF MARPOL73/78 AND THE IBC CODE

These products will be shipped only in approved card boxes.

15. REGULATORY INFORMATION

15.1 SAFETY, HEALTH AND ENVIRONMENTAL REGULATIONS/LEGISLATION SPECIFIC FOR THE SUBSTANCE OR MIXTURE

This safety data sheet meets the requirements of the Regulation (EC) 453/2010 to amending Regulation (EC) 1907/2006 and (EC)2016/1179 modifying (EC) 1272/2008.

Calculation The calculated toxicity (ATE) of the mixtures according (EC) 1272/2008, Annex I:

Wash and Incubation Buffer	12,200,000	mg/kg body weight	no classification
Conjugate Solution	248,100	mg/kg body weight	no classification
Substrate Solution	595,000	mg/kg body weight	no classification

According (EC) 1272/2008, Annex I: no classification not hazardous to water.
calculated L(E)C50 of the mixtures:

Wash and Incubation Buffer	775	mg/l	no classification (> 100 mg/l)
Conjugate Solution	527	mg/l	no classification (> 100 mg/l)
Substrate Solution	9,080	mg/l	no classification (> 100 mg/l)

Water endangering class according to VwVwS (Germany): Water endangering class 1

Employment limitations:
Reference is made to the restrictions of employment specified in the Youth Employment Act and the Maternity Protection Act.

Other regulations, limitations and prohibitive regulations:
Substance of very high concern (SVHC) according EG 1907/2006 (REACH), Article 57: N-Methyl-2-pyrrolidone (CAS 872-50-4)

15.2 CHEMICAL SAFETY ASSESSMENT

No data available.

16. OTHER INFORMATION

Fully text to the H-Sentences mentioned in heading 3:

H228	Flammable solid.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
H360D	May damage the unborn child.

Categories of the Acute Toxicity (ATE) according EC 1272/2008:

Category 1	0< ATE ≤5	(oral in mg/kg body weight)
Category 2	5< ATE ≤50	(oral in mg/kg body weight)
Category 3	50< ATE ≤300	(oral in mg/kg body weight)
Category 4	300< ATE ≤2,000	(oral in mg/kg body weight)

Further information:

The information stated above is based on our actual knowledge and is intended to describe our products concerning safety recommendations. The information does not assure product properties and is therefore no basis for legal action.

The REACH registration numbers in heading 3 is not available as the substances or its use is exempted from registration according to article 2 REACH Regulation EC 1907/2006, or the annual tonnage does not require a registration, or is envisaged for a later registration deadline.

Changes with respect to the previous version:

- Changes in the articles 2 and 15 due to the regulation (EC) 2016/1179 modifying (EC) 1272/2008